K062042 p1of3

SEP - 6 2006

plethora SOLUTIONS

Lupus House
11-13 Macklin Street
Covent Garden
London WC2B 5NH

T +44 (0) 207 2698 630
F +44 (0) 207 2428 518
E mail@plethorasolutions.co.uk

2. 510(k) Premarket Notification Summary

(Summary Prepared on July 18, 2006

A. 510(k) Owner: Plethora Solutions Limited
Official FDA Correspondent: Miranda Tighe, Project Manager for In-Licensed Programmes
Lupus House, 11-13 Macklin Street
Covent Garden, London, WC2B 5NH
United Kingdom
(T) +44 (0) 207 2698 630
(F) +44 (0) 207 2428 518
e-mail: miranda.tighe@plethorasolutions.co.uk

B.

Trade Name:	Sexual Assessment Monitor (SAM)
Common Name:	Penile Tumescence/Ejaculatory Latency Monitor
Product Code:	LIL (Unclassified)
Advisory Committee:	Gastroenterology/Urology

C. Substantial Equivalence Predicate Device(s):

Manufacturer	Device Name	510-K Number	Decision Date
Dacomed Corporation	Rigiscan System	K841202	07/06/1984
Dacomed Corporation	Rigiscan Plus Rigidity Assessment System	K941781	08/25/1994

D. Device Description:

The Plethora Solutions Sexual Assessment Monitor (SAM) is intended for use as a diagnostic tool for use in the quantifiable assessment and monitoring of penile tumescence and ejaculatory latency.

The Sexual Assessment Monitor (SAM) includes the following components:

- SAM application software
- device control box
- vibrator with integral 3m lead
- serial port communications cable
- 0.5m sensor lead adapter
- device charger.

- device charger.

E. Intended Use of Device:

The Plethora Solutions Sexual Assessment Monitor (SAM) is intended for use as a diagnostic tool for use in the quantifiable assessment and monitoring of penile tumescence and ejaculatory latency.

F. Substantial Equivalence Discussion

SAM is substantially equivalent to the identified predicate devices based on the following:

1. The INTENDED CLINICAL USE for the Plethora Sexual Assessment Monitor (SAM) is **SUBSTANTIALLY EQUIVALENT** to the predicate devices.

2. The Plethora Sexual Assessment Monitor (SAM) and the 2 predicate devices are both substantially equivalent Medical Device Systems **FOR USE IN THE SAME ANATOMICAL LOCATION and BY the SAME SYSTEM USERs in the SAME CLINICAL SETTINGS.**

3. The OPERATIONAL FEATURES/TECHNOLOGICAL CHARACTERISTICS of the Plethora Sexual Assessment Monitor are the **SAME or SIMILAR** to those offered by the predicate device.

4. The **SAFETY ASPECTS** of the Plethora Sexual Assessment Monitor (SAM) are the **SAME or very SIMILAR** to those offered by the predicate devices. SAM is as safe or safer than the two predicate devices and the technological characteristics of SAM and its intended clinical uses provide NO ADDITIONAL SAFETY RISK TO patients or System operators.

5. The Plethora Sexual Assessment Monitor (SAM) has been observed to be an **EFFECTIVE** diagnostic tool **(AS OR MORE EFFECTIVE THAN RIGISCAN DEVICE)** in a clinical setting, as documented by Dinsmore WW, Ralph DJ, Kell P et al, Evaluation of the Sexual Assessment Monitor, a diagnostic device used to electronically

quantify ejaculatory latency time: findings from three studies. BJU Inter. 2006;1-6 with further evidence provided in this submission from the 3 full clinical study reports referenced.

G. Bench and Clinical Testing Supporting Documentation

SAM received CE MARK approval in 2005 with demonstrated compliance to EN 60601-1:1990 and EN 60601-1-2:2002. Documentation from 3 prospective formal clinical studies including a peer-reviewed report of these clinical studies provides further clinical safety documentation of the Plethora Solutions Sexual Assessment Monitor in conjunction with the clinical efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP -6 2006

Plethora Solutions Limited
c/o Ms. Kimberly Doney
Consultant
54 Forest Street
LEXINGTON MA 02421

Re: K062042
Trade/Device Name: Plethora Solutions Sexual Assessment Monitor (SAM)
Regulation Number: None
Regulatory Class: Unclassified
Product Code: LIL
Dated: July 18, 2006
Received: July 19, 2006

Dear Ms. Doney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Original Premarket Notification K062042

Device Name: Plethora Solutions Sexual Assessment Monitor (SAM)

Indications for Use:

The Plethora Solutions Sexual Assessment Monitor (SAM) is intended for use as a diagnostic tool for use in the quantifiable assessment and monitoring of penile tumescence and ejaculatory latency.

Prescription Use __X____
(Part 21 CFR 801 Subpart D)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K062042